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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/782,306

02/14/2001

Uwe Wenzel

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12/05/2007

NOVAK DRUCE DELUCA & QUIGG, LLP

1300 EYE STREET NW

SUITE 1000 WEST TOWER

WASHINGTON, DC 20005

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

12/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/782,306

**Applicant(s)**

WENZEL ET AL.

**Examiner**

Eric S. Olson

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

This office action is a response to applicant's communication submitted December 20, 2006, wherein the rejections of record in the previous office action are traversed. This application claims benefit of provisional application 60/185179, filed February 25, 2000.

Claim 1 is pending in this application.

Claim 1 as amended are examined on the merits herein.

In accordance with the petition decision of record March 5, 2007, the finality of the previous office action is withdrawn. All pending claims are examined on the merits herein, in view of Applicant's arguments submitted December 20, 2006.

Applicant's arguments, submitted December 20, 2006, with respect to the rejection of instant claim 1 under 35 USC 102(b) for being anticipated by Watanabe et al., have been fully considered and found to be persuasive to remove the rejection as the term "neutraceutical" is seen to be defined in the instant specification in such a way as to not be identical with the compounds and compositions described by Watanabe et al. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (US patent 5650433, of record in previous action) in view of Hirschberg. (US patent 6440449, cited in PTO-892) Watanabe et al. discloses flavonoid chondroprotective agents. (column 2, lines 10-24) The list of preferred embodiments includes Flavone, which is the compound recited in instant claim 1. (columns 3-4, table 1, no. 1) These compounds inhibit the destruction of chondrocyte matrix and are useful as chondroprotective agents for treating various types of arthropathy including osteoarthritis. (column 5, lines 4-13) The active agent can be prepared in any conventional formulation in mixture with any pharmaceutically acceptable carrier or diluent. (column 5, lines 14-23) Watanabe et al. does not disclose a composition that is a nutraceutical according to the definition given in p. 9, lines 26-30 of the specification, containing only beneficial, health-promoting, naturally occurring components.

Hirschberg discloses a method of infusing a phytochemical, nutraceutical, or other food additive into a food product. (column 2, lines 18-47) Examples of foods that can be treated in this manner include fruits, vegetables, juices, and meats. (column 3, lines 29-42) A food product to which a medicinal agent has been added in this manner is considered to be a nutraceutical according to the definition given in p. 9, lines 26-30

of the specification. It is noted that this definition is very broad and would encompass any food product infused with a therapeutic agent.

It would have been obvious to one of ordinary skill in the art at the time of the invention to infuse the flavone compound of Watanabe et al. into the infused foods of Hirschberg. One of ordinary skill in the art would have been motivated to combine the inventions in this manner because Hirschberg already discloses that various phytochemicals and other compounds can be added to foods in this manner, and because Watanabe et al. discloses that any conventional dosage form, which limitation includes the infused foods of Hirschman, can be used to deliver the flavone compounds. One of ordinary skill in the art would reasonably have expected success because preparing a known active agent as a known dosage form is well within the ordinary and routine level of skill in the art.

Furthermore, there exist many extremely common, naturally occurring pharmaceutical excipients (e.g. water, sucrose, vegetable oil) that one of ordinary skill in the art would recognize as being useful for making formulations of an active agent such as the flavone described by Watanabe et al. Formulations using these ingredients would be compositions including only naturally occurring components as described in the instant specification.

Thus the invention taken as a whole is *prima facie* obvious.

### **Conclusion**

No claims are allowed in this application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson



Patent Examiner  
AU 1623  
11/29/07

Anna Jiang



Supervisory Patent Examiner  
AU 1623